In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 19, 2024

SUSAN WEST,	*	
Petitioner,	*	No. 21-1515V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew D. Downing, Downing, Allison & Jorgenson, Phoenix, AZ, for petitioner.
Mary E. Holmes, U.S. Department of Justice, Washington, D.C., for respondent.

FINDING OF FACT[1]

On June 28, 2021, Susan West ("petitioner") filed a timely petition in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). Petitioner alleges that as a result of receiving an influenza vaccination on October 19, 2019, she suffers from optic neuritis. *Id.* at Both parties have requested a ruling on whether petitioner has demonstrated that she suffered the residual effects of her alleged vaccine-related injury for more than six months after the administration of her flu vaccine on October 9, 2019, without the need for a hearing. As detailed below, I find that the severity of petitioner's symptoms satisfies the six-month requirement.[3]

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[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. This means the opinion will be available to anyone with access to the Internet. Before the opinion is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the [opinion]." *Id.* If neither party files a motion for redaction within 14 days, the opinion will be posted on the court's website without any changes. *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-1 to 34 (2012) ("Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] Pursuant to Section 13(a)(1), in order to reach this determination, I have considered the entire record including all of the medical records, affidavits, and other evidence submitted by petitioner. This ruling discusses only the elements of the record I found most relevant to determining whether petitioner met the severity requirement of the Vaccine Act.

I. Procedural History

On June 28, 2021, petitioner filed a petition concerning her receipt of an influenza vaccination on October 9, 2019, at her primary care physician's practice in Goodyear, Arizona. Pet. at 1; Petitioner's (Pet'r.) Exhibit (Ex.) 2 at 24. Petitioner subsequently filed supporting medical records as well as a statement of completion on February 23, 2022. *See* Pet'r. Ex. 2-18 (ECF No. 6, 7, 9, 13, 18); Statement of Completion (ECF No. 20). Petitioner also filed an affidavit from petitioner to support her claim. *See* Pet'r. Ex. 1 (ECF No. 6).

On March 16, 2022, the case was reassigned to my docket. ECF No. 27. Respondent filed his Rule 4(c) Report on October 14, 2022, recommending that compensation be denied on the grounds that petitioner "has not provided a reliable medical theory causally linking the vaccination to the injury, failed to establish what the appropriate time frame is for onset of her alleged injury, and failed to establish that the onset of her condition fell within that timeframe." Respondent's (Resp't.) Report at 9 (ECF No. 33). Additionally, respondent argued that compensation should be denied because "petitioner's vision complaints pre-date her October 9, 2019 flu vaccination." *Id.*

Petitioner subsequently filed an expert report from Dr. Devin Mackay on April 10, 2023. Pet'r. Ex. 20 (ECF No. 36). On June 23, 2023, respondent filed an expert report from Dr. Marc Bouffard. Resp't. Ex. A (ECF No. 38). Petitioner filed a supplemental expert report from Dr. Mackay on July 10, 2023. Pet'r. Ex. 25 (ECF No. 40).

On September 20, 2023, I held a telephonic status conference to discuss the six-month severity issue. *See* Scheduling Order (ECF No. 44). I noted that both experts agree that petitioner had optic neuritis, but that respondent's expert disputes whether the flu vaccine can cause optic neuritis as well as whether petitioner demonstrated the required six-months of symptoms related to her optic neuritis. *Id.* I noted that Dr. Mackay provided a "sound and reliable theory for how the influenza vaccination can cause optic neuritis" and that his theory "is supported by the medical literature he relied upon." *Id.* Regarding the main issue of whether petitioner had six-months of residual symptoms, I explained that "it does appear that petitioner's residual symptoms from the optic neuritis are relatively minor" but emphasized that "petitioner's statements regarding her peripheral vision being 'off' and having a 'gray haze' do appear consistent with residual effects of optic neuritis." *Id.*

Pursuant to the Scheduling Order from October 13, 2023, respondent filed a status report on November 13, 2023, indicating that he is not amenable to settlement negotiations at this time and would like to continue litigating the case." Resp't. Report (ECF No. 46). Respondent filed a supplemental expert report from Dr. Bouffard on December 5, 2023. Resp't. Ex. C (ECF No. 47).

After receiving a request from both parties for the Court to resolve whether petitioner has demonstrated that she has suffered the residual effects of her alleged vaccine-related injury for

more than six-months after the administration of her flu vaccine on October 9, 2019, I directed the parties to submit briefs regarding the factual issue. *See* Scheduling Order (ECF No. 48). On May 13, 2024, in accordance with the briefing schedule, petitioner submitted their brief regarding severity. *See* Pet'r Brief (Br.) (ECF No. 49). Respondent subsequently filed their responsive brief on June 25, 2024. *See* Resp't. Br. (ECF No. 50). Accordingly, the matter is ripe for adjudication.

II. Relevant Legal Standard

As a preliminary matter, to be eligible for compensation under the Vaccine Act, a petitioner must demonstrate that she has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine…or suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." 42 U.S.C. § 300aa-11(c)(1)(D)(i)-(iii) ("severity requirement"). Like other elements of petitioner's proof, the severity requirement must be established by a preponderance of the evidence. *See* § 300aa-13(a)(1)(A); *see also Song v. Sec'y of Health & Human Servs.,* 31 Fed. Cl. 61, 65-66 (1994), *aff'd* 41 F.3d 1520 (Fed. Cir. 2014) (noting that petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence).

A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable that its nonexistence." *Moberly v. Sec'y of Health & Human Servs.,* 592 F.3d 1315, 1322, n.2 (Fed. Cir. 2010). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding on medical records alone. *See* § 300-13(a)(1)); *see also Colon v. Sec'y of Health & Human Servs.*, 156 Fed. Cl. 534, 541 (2021).

The process for making determinations in the Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs.,* 993 F.2d 1525, 1528 (Fed. Cir. 1993). While medical records are not presumed to be complete and accurate, medical records while seeking treatment are generally afforded more weight than statements made by petitioner after the fact. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Further, medical records may not be accurate and complete as to all the patient's physical conditions. *Kirby v Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves,

inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Factual Record

a. Petitioner's medical records

Prior to the vaccination, petitioner visited Nationwide Vision for eye exams routinely and had been diagnosed with "dry eye syndrome of bilateral lacrimal glands" in 2017. *See* Pet'r. Ex. 17 at 9. Petitioner wore corrective lenses and contacts, and her prescription was updated annually, with the most recent adjustment on August 28, 2019. *See id.* at 10, 16, 23. Petitioner received the flu vaccine on October 9, 2019, during a visit with her primary care physician, Dr. Christina Martin. Pet'r. Ex. 2 at 25.

On October 22, 2019, petitioner had an appointment with Dr. Tyler French, an ENT at Biltmore Ear Nose and Throat for "left otalgia[4]." *See* Pet'r. Ex. 14 at 7. Petitioner reported "feeling generalized imbalance that can be fairly severe and worsens when her eyes are closed." *Id.* Petitioner noted that she had previously had episodes with similar symptoms twice in the "last couple of years." *Id.* She did not have any change in her hearing during the episodes, but does have "constant left tinnitus." *Id.* Petitioner was assessed with "dizziness; left ear pain; left tinnitus aurium." *Id.* at 9.

On October 27, 2019, petitioner visited urgent care for "cold symptoms." Pet'r. Ex. 6 at 59. She reported nasal congestion, post-nasal drainage, rhinitis, rhinorrhea, and sinus pressure. *Id.* Petitioner indicated that these symptoms had been present for two weeks. *Id.* The patient plan indicated that petitioner's diagnosis was "acute rhinosinusitis" and she was prescribed Augmentin for her symptoms. *Id.* at 61.

[4] Otalgia is "pain in the ear," or an "earache." *33rd Dorland's Illustrated Medical Dictionary*, 1331 (2020).

Four days later, on October 31, 2019, petitioner visited Dr. Bentley Skibell at Arizona Eye Specialist, complaining of "eye pain, which began two weeks ago." Pet'r. Ex. 5 at 29. She described the eye pain as "constant, affecting the right eye, affecting her eyes/vision, and worsening." *Id.* Dr. Skibell noted that petitioner has "no significant past ocular history." *Id.* The assessment characterized petitioner's condition as "orbital pain in or around right eye" and provided the following plan: "right retro-orbital pain, worse with eye movement; normal color, some optic nerve NFL fullness both eyes by OCT; went to urgent care last Sunday, empirically treated with Amoxicillin, did not improve; possible optic neuritis; does have tinnitus constant, seen by ENT; two year history of ear left pain." *Id.* at 33. Dr. Skibell noted that petitioner denied "headaches, transient visual loss, or diplopia." *Id.* Dr. Skibell recommended that petitioner have a Brain MRI, which was scheduled for November 5, 2019. Pet'r. Ex. 14 at 12.

On November 5, 2019, petitioner visited the emergency department ("ED") of St. Joseph's Hospital complaining of "blurred vision in her right eye with right temporal pain." at Pet'r Ex 9 at 2. The History of Present Illness states that petitioner had been complaining of this "for several months, associated with vertigo and ear pain, she also complains of changes in gait and smell, temporal pain, visual disturbances (cloudy view of objects, "speckles in eye"), and blurred vision beginning three weeks ago that was preceded by bilateral dryness and then a pressing pain." *Id.* Her cranial nerve exam was negative for a nystagmus, gaze deviation or lid lag, and she did not have any facial droop noted. *Id.* at 3.

An MRI C-Spine with contrast, MRI Orbits with and without contrast, MRI Brain with and without contrast, MR Angio Head with contrast, and an MRI Angio Neck with contrast were performed. Pet'r. Ex. 14 at 10-15. The MRI C-Spine had findings indicating "spondylitic ridging at C5-C6 with mild cord flattening; normal cord signal; no abnormal enhancement in the spinal cord." *Id.* at 10. The MRI Orbits findings indicated right eye visual changes, including "right optic nerve demonstrates mildly increased FLAIR signal abnormality in the mid and anterior aspect of the nerve, also demonstrating contrast enhancement." *Id.* at 12. The conclusion of the MRI report indicated "right-sided optic nerve inflammation and enhancement most suggestive of optic neuritis." *Id.* at 13. The MRI Brain also indicated "right optic nerve enhancement." Pet'r. Ex. 9 at 9. The MR Angio Neck and the MR Angio Head results were unremarkable. *Id.* The ED discharged petitioner with a diagnosis of right optic neuritis and prescribed a prednisone taper. *Id.* at 109, 121.

Also on November 5, 2019, petitioner had an occupational therapy initial evaluation with the goal of "completing full visual field testing to evaluate visual fields in more detail." *Id.* at 178. During visual acuity testing, petitioner's results indicated "distance vision at 10 feet left eye 20/20; right eye 20/70. Near vision at 16" left eye 20/30; right eye 20/200." *Id.* On assessment, petitioner "appeared to have reduced visual acuity to right eye with what appears to be scotoma type pattern of patchy vision; does not impact her ability to read signage, scan her environment, read a newspaper article, or mobilize safely." *Id.* at 179. Petitioner also stated she experienced "slightly blurry with binocular vision and prescription glasses," however, the treating physician noted that "this does not affect her ability to read with clarity and understanding." *Id.* at 180. The Overall Screen Assessment stated the following: "petitioner states with right eye vision only, items in visual field appear as though they are covered by a thick translucent bag, making everything 'hazy' or 'smoky;' able to distinguish between different colors." *Id.* at 181.

Petitioner attended a follow-up appointment with Dr. Skibell on November 7, 2019. Pet'r. Ex. 5 at 24. The patient problem from the visit states "orbital pain in or around eye; right eye." *Id.* After reviewing petitioner's records from Dr. Al-Hasan, Dr. Skibell recommended that petitioner continue with the prednisone taper and schedule a follow-up appointment. *Id.* at 27. Petitioner had a follow-up appointment with physician Dr. Skibell on November 13, 2019. *Id.* at 18. The plan for managing petitioner's optic neuritis indicated "right optic neuritis, improving status post course of IV steroids. Now on prednisone taper, managed by neurologist, feeling better." *Id.* at 22. Dr. Skibell noted "discussed natural history- may have some permanent visual loss but too early to determine final visual outcome- good visual recovery at present." *Id.* However, on November 19, 2019, petitioner called Dr. Yazan Al-Hasan, a neurologist at St. Joseph's Hospital, complaining of "worsening eye pain with movement while tapering prednisone from 20 mg to 10 mg." Pet'r. Ex. 9 at 35. Dr. Al-Hasan recommended that petitioner stay at 20 mg for 1 month prior to a trial of reducing steroid dosing. *Id.* On January 22, 2020, petitioner visited her primary care physician, Dr. Martin, for a medication refill. Pet'r. Ex. 2 at 18.

On January 29, 2020, petitioner visited neurologist Dr. Al-Hasan for a follow-up appointment. Pet'r. Ex. 11 at 9. The clinic notes states, "woman with left [5]optic neuritis treated with methyl prednisone and has not had substantial improvement in vision." *Id.* Dr. Al-Hasan noted that petitioner "still has slightly blurring left eye compared to right eye but fairly minimal." *Id.* The impression indicated "subacute optic neuritis; no associated abnormal cord signal; etiology likely idiopathic." *Id.* at 11. On May 6, 2020, petitioner had a follow-up with Dr. Al-Hasan, who referred petitioner to NeuroOphthalmology, stating that petitioner "has history of optic neuritis, has persistent poor vision and pain, 05/06/20." *Id.* at 40.

Petitioner had a telehealth consultation with Dr. Damian Berezovsky at Barrow Neurological Institute for "right optic neuritis," on June 24, 2020. Pet'r. Ex. 12 at 17. Petitioner reported that "in October 2019, she developed severe right retroorbital pain as well as symptoms of severe dry eye." *Id.* at 19. She further stated that "she did not immediately notice right eye vision loss, but 5 days later she developed 'gray' vision in the right eye." *Id.* Petitioner indicated that her ophthalmologist told her that "there was fluid behind [her] eyes." *Id.* The MRI of her brain/orbits showed optic nerve enhancement suggestive of inflammatory optic neuritis. *Id.* at 18-19. Petitioner reported that the 5-day course of IV Solu-Medrol "quickly resolved her eye pain" but also reported that despite improving, her vision was "not back to her previous baseline." *Id.* at 20. Petitioner denied any recurrences of eye pain but reported that her right eye vision "frequently fluctuates." *Id.* The limited examination of petitioner found that that she had "no obvious spontaneous or gaze-evoked nystagmus," and "no ptosis or proptosis." *Id.* at 21. Dr. Berezovsky's assessment was "right optic neuritis," and noted that petitioner has not had any recurrences of painful vision loss, but that "there have been fluctuations in her vision and eye discomfort." *Id.* Dr. Berezovsky requested that petitioner obtain a set of neuro-ophthalmic tests to establish her baseline which would be used for future comparison to evaluate for progressive optic atrophy, or if she had a recurrence of her symptoms. *Id.*

[5] This reference appears to be in error in a sign off on a resident's exam as all other references are to right optic neuritis.

Petitioner underwent neuro ophthalmic testing on July 31, 2020. Pet'r. Ex. 12 at 4. The results from the Fast Humphrey Automated Test was as follows:

> Humphrey visual field examination is normal in both eyes, without visual field defects in either eye. OCT of RNFL and macular ganglion cell layer are also within normal limits. Today's neuro-ophthalmic testing results are not suggestive of a right or left optic neuropathy (due to the absence of optic atrophy). It is possible that her abnormal MRI findings in November 2019 were artifactual. Even mild episodes of inflammatory optic neuritis, with complete resolution of vision loss, would be expected to result in optic atrophy on neuro-ophthalmic testing. Recommend ongoing neuro-ophthalmology follow-up to monitor for any future vision changes or optic neuropathy.

Id.

On September 24, 2020, petitioner visited Dr. Robert D. Spruance at Barnet Dulaney Perkins Eye Center for an updated prescription. Pet'r. Ex. 18 at 2. Dr. Spruance noted "optic neuritis" under Past Ocular History. *Id.* Petitioner complained of "constant blurred vision in both eyes that affected both near and far vision." *Id.* After petitioner's external examination was normal, Dr. Spruance wrote two glasses prescriptions and recommended that petitioner follow-up in one year. *Id.* On October 24, 2020, petitioner returned to Nationwide Vision complaining of "blurred vision both far and near." Pet'r. Ex. 17 at 30. Under patient history, optic neuritis is listed as "active" as of October 24, 2020. *Id.* at 31. After an examination, petitioner received an updated prescription for glasses. *Id.*

At a follow-up appointment with Dr. Skibell for optic neuritis on April 15, 2021, petitioner complained of blurry vision when working at her computer, dry eye, irritation, itching, and light sensitivity, along with eye fatigue. Pet'r. Ex. 5 at 3. Dr. Skibell noted that "petitioner has a history of blood vessels bursting in her right eye onset 3-22-21" and that petitioner "last used over the counter artificial tears 1 week ago." *Id.* Under problem list, the medical records list "optic neuritis" with an onset date of 11-13-2019 and a status of "active." *Id.* During an examination, Dr. Skibell observed "right eye some inferior depression, left eye essentially full." *Id.* at 6. Dr. Skibell also noted "dry eye with decrease tear break up time, increased tear osmolarity both eyes" and recommended artificial tears and tear gel for treatment. *Id.* at 7. Regarding petitioner's optic neuritis, Dr. Skibell recommended that she continue following up with Dr. Berezovsky for treatment. *Id.* at 8.

On May 26, 2021, petitioner had a follow-up with Dr. Berezovsky and reported that "she experienced visual disturbances (colors on a paper page 'jumping around') in early April 2021." Pet'r. Ex. 12 at 41. Petitioner reported that dry eye treatment and discontinuation of the contact lens has been effective. *Id.* During examination of the right optic nerve, Dr. Berezovsky noted "C/D 0.4 OU with subtle optic disc pallor OD." *Id.* at 42. From this, Dr. Berezovsky stated: "Although right optic atrophy was not obvious when petitioner was initially seen by me, on examination today there is temporal pallor of the right optic disc, along with thinning of the RNFL and macular ganglion cell layer in the right eye." *Id.* at 43. He also wrote that, "it would be reasonable to continue following her in the neuro-ophthalmology clinic on a regular basis, but there is no indication of an ongoing inflammatory process at this time." *Id.*

Petitioner had a follow-up with Dr. Skibell on June 16, 2021, where she reported that her dry eye symptoms were "feeling better with artificial tears" and denied any recent vision changes. Pet'r. Ex. 19 at 14. Petitioner's examination was normal in both eyes and Dr. Skibell recommended that she follow-up in one year. *Id.* at 16. On August 12, 2021, petitioner returned to Dr. Skibell complaining of a "blood shot right eye." *Id.* at 10. Petitioner stated that "since being diagnosed with optic neuritis, the right eye tends to become red with blood" and associated the symptom with "itchiness, scratchy, and pressure." *Id.* Dr. Skibell noted a subconjunctival hemorrhage in petitioner's right eye and recommended that petitioner follow-up with her primary care physician for management. *Id.* at 12. Dr. Skibell also recommended that petitioner return for an ophthalmologist follow-up in one year. *Id.* at 13.

On July 1, 2022, petitioner returned to Dr. Skibell for a follow-up appointment. Pet'r. Ex. 19 at 2. During a fundus exam, the right eye exhibited "absent vitreous cells; absent pigment" while the left eye exhibited a "clear vitreous." *Id.* at 5. The assessment also noted a "history of floaters in the right eye a few months ago" that had "since resolved." *Id.* Dr. Skibell recommended that petitioner start Restasis for dry eye treatment and for petitioner to follow-up in three months for a surface check. *Id.* On February 27, 2023, petitioner had a follow-up with Dr. Skibell concerning her dry eyes. Pet'r. Ex. 28 at 22. Petitioner reported no changes since her last visit and stable vision but associated the dry eyes with "irritation, itching, and redness." *Id.* After an unremarkable physical examination, petitioner reported a negative rheumatology work up and expressed wanting to try Restasis for another three months before considering other options. *Id.* at 24. Dr. Skibell agreed and scheduled a follow-up for around four months later. *Id.*

At a follow-up with Dr. Skibell on June 12, 2023, petitioner reported improvement in dry eye symptoms but complained of "difficulty when viewing TV, reading closed caption, or news scrolls on TV" that petitioner felt "affected both eyes and was worsening." *Id.* at 15. Petitioner also reported that the floaters in her eyes were worsened by "intensive visual activity (reading, computer)." *Id.* Optic neuritis was listed under the Assessment and Dr. Skibell recommended that petitioner return in 3 months for a follow-up, as well as schedule an appointment for a renewed glasses/contacts prescription. *Id.* at 18. Petitioner most recently visited Dr. Skibell on September 22, 2023, when she reported being told by an optometrist that "her right eye vision was worse." *Id.* at 9. Petitioner denied experiencing eye pain or diplopia and reported her vision being stable. *Id.* Dr. Skibell evaluated petitioner and recommended that she follow-up with him in six months unless new floaters appear. *Id.* at 12.

b. Petitioner's affidavit

Petitioner filed an affidavit dated June 14, 2021. *See* Pet'r. Ex. 1. In her affidavit, petitioner states that she had no vision problems prior to receiving the flu vaccination on October 9, 2019, and her subsequent optic neuritis diagnosis. *Id.* at ¶ 1. Petitioner places the onset of her symptoms on October 18, 2019, stating that she began to experience "pain with movement in her right eye and a terrible headache over that eye." *Id.* at ¶ 3.

Regarding petitioner's first visit with Dr. Skibell on October 31, 2019, petitioner states that Dr. Skibell "told her that there was swelling of her optic nerve in her right eye." Id. at ¶ 5.

Petitioner further noted experiencing blurry vision and a "gray cloud over the right eye" starting after work on November 4, 2019. *Id.* at ¶ 6. As a result of petitioner's visit to the Emergency Room on November 5, 2019, petitioner reports missing the remainder of the week and the following week of work. *Id.* at ¶ 8. Further, petitioner states being "unable to handle the steroids long-term" and requesting that Dr. Al-Hasan prescribe a faster taper. *Id.*

Petitioner states that at her appointment with Dr. Al-Hasan on January 29, 2020, she reported that her vision was "not yet restored" and that she was still experiencing pain. *Id.* at ¶ 10. Petitioner notes that Dr. Al-Hasan assured her by stating that these symptoms "were all part of optic neuritis." *Id.* Petitioner reports the sentiment being reiterated by Dr. Al-Hasan at a follow-up appointment on March 5, 2020. *Id.* at ¶ 11.

Petitioner also reports experiencing "extreme sensitivity to the sunlight driving into work" on April 7, 2021. *Id.* at ¶ 17. She further states the "fluorescent lights and computer monitor gave her glare and vision problems," specifically that she was "unable to focus on a highlighted document because it appeared that the lines were moving." *Id.*

In describing the residual effects, petitioner states that "my vision is not the same; every day is different." *Id.* at ¶ 20. Petitioner describes her current symptoms as:

> "Some days it feels as though a needle is poking my eye. Other days I get double vision after reading or working. There is eye pain, a gray haze, or severe dryness along with an uncomfortable scratchiness. When I turn the lights off at night or close my eyes in the dark, I see bright white light. My peripheral vision is off so frequently that I see things that are not there. I wear two pairs of glasses to read fine print, even with my new prescription."

Id.

Petitioner also reports experiencing "the same, horrible headache over my right eye nearly every day." *Id.* at ¶ 21.

c. Expert Reports Regarding Severity

i. Petitioner's Expert: Devin D. Mackay, M.D.

Petitioner submitted two expert reports from Dr. Devin D. Mackay. *See* Pet'r. Ex. 20; Pet'r. Ex. 25. Regarding onset, Dr. Mackay states that petitioner developed "pain with right eye movement" nine days after the vaccination on October 18, 2019. *See* Pet'r. Ex. 20 at 10; Pet'r. Ex. 1 at 1. This evolved into vision loss in the right eye on November 4, 2019. *Id.* The next day, Dr. Mackay notes that petitioner reported to the emergency department with right eye vision loss and MRI results indicated "right-sided optic nerve inflammation and enhancement most suggestive of optic neuritis." *Id.*; Pet'r. Ex. 5 at 46. Dr. Mackay concluded that petitioner was diagnosed with optic neuritis at this time. *Id.*

In discussing the length of symptoms of petitioner's optic neuritis, Dr. Mackay noted that petitioner's treating neuro-ophthalmologist, Dr. Damian Berezovsky, upheld the optic neuritis diagnosis at petitioner's appointment on May 26, 2021. Pet'r. Ex. 20 at 10; Pet'r. Ex. 12 at 43. Specifically, Dr. Mackay states that:

> Dr. Berezovsky also found evidence of permanent damage to petitioner's right optic nerve (optic atrophy) from her 2019 episode of optic neuritis, manifested by pallor of the right optic disc, thinning of the peripapillary retinal nerve fiber layer in the right eye, and macular ganglion cell thinning in the right eye.

Id.

In his supplemental expert report, Dr. Mackay agreed with respondent's expert, Dr. Bouffard, that petitioner's dry eyes predated her vaccination but disputed Dr. Bouffard's argument that "even if petitioner did have optic neuritis from the vaccination, problems referable to it were transient (resolving in <6 months), have not left her with any visual disability, and are not the source of the complaints cited in her affidavit." *See* Pet'r. Ex. 25 at 3; Resp't. Ex. A at 9. Instead, Dr.MacKay asserted that petitioner's symptoms of "gray haze" and "fluctuating visual function," were symptoms consistent with optic neuritis. Pet'r. Ex. 25 at 3; *see also* Pet'r. Ex. 1 at 3.

Dr. Mackay stated, "I have seen patients, and I am sure Dr. Bouffard has as well, who have objectively recovered well from optic neuritis based on parameters measurable during a clinic visit (visual acuity, color vision, visual field testing, etc.), but they continue to have important vision symptoms related to the optic nerve damage that impair the quality of life, such as difficulty with low-contrast visual scenes and a decreased sharpness to the vision that can interfere with daily activities." Pet'r. Ex. 25 at 3. He noted that a study by Sabadia et al. found that "even when high-contrast visual acuity was 20/40 or better after recovering from optic neuritis, scores on the vision-specific quality of life questionnaire were significantly worse than controls." *Id.*; Pet'r. Ex. 35. Sabadia stated, ".studies have shown persistent loss of contrast sensitivity and color vision after acute ON. Visual impairment, therefore, persists in many patients who have otherwise experienced what is referred to as good recovery." Pet'r. Ex. 35 at 1. Dr. Mackay observed that Sabadia found that in "the group with 20/40 vision or better high-contrast visual acuity, there were clinically-meaningful reductions in vision-specific quality of life that reflect persistent impairment of low-contrast letter acuity and losses of retinal nerve fiber layer thickness and ganglion cell later + inner plexiform layer thickness. Such reductions are present even when recovery of visual acuity is 20/20 or better in affected eyes." Pet'r. Ex. 25 at 3; Pet'r. Ex. 35 at 4-5. The study authors wrote, "This is consistent with the clinical observation among neuro-ophthalmologists that patients perceive visual deficits long after the acute optic neuritis event and achievement of maximal recovery." Pet'r. Ex. 35 at 4. Sabadia also found that retinal nerve fiber layer thinning was found as early as one-month post-acute optic neuritis and is seen in 74% of affected eyes. *Id.* Interpreting the study, Dr. Mackay wrote:

> In other words, the recovery of visual acuity to 20/20 (would be considered normal) after optic neuritis does not indicate a full recovery of normal visual function and OCT in patients shows evidence of permanent optic nerve damage. Persons with a history of

> optic neuritis typically have a reduced vision-specific quality of life, even with what might objectively be considered a good or excellent recovery.

Pet'r. Ex. 25 at 3.

Applying the results from Sabadia et al. to petitioner's case, Dr. Mackay stated:

> The pallor of the petitioner's right optic disc noted by Dr. Berezovsky during his follow-up examination of the petitioner on May 26, 2021, and the macular ganglion cell layer thinning he found in the right eye are direct evidence of the permanent damage to the right optic nerve caused by optic neuritis and in line with the findings from the study by Sabadia et al. that correlate post-optic neuritis ganglion cell thinning with decreased vision-specific quality of life, even with good recovery of visual acuity.

Id. at 4.

Therefore, Dr. Mackay concluded that "it continues to be my opinion that petitioner suffered an enduring injury due to optic neuritis as a result of the influenza vaccination she receives on October 9, 2019." *Id.*

ii. Respondent's Expert: Dr. Marc A Bouffard, M.D.

Respondent's expert Dr. Marc A Bouffard authored an initial report and a supplemental report in this matter. *See* Resp't. Ex. A; Resp't. Ex. C. In his initial report, Dr. Bouffard stated:

> It is important to recognize that petitioner's optic neuritis has not caused significant residual visual dysfunction, as evidenced by many examinations demonstrating 20/20 acuity in each eye, full color vision, and full visual fields.

Resp't. Ex. A at 6.

Dr. Bouffard referenced an article by Beck et al., which explained the clinical course and recovery of optic neuritis, to support his opinion that petitioner's symptoms were "mild" and did not cause "any significant residual visual dysfunction." *Id.*; Resp't. Ex. A. 6.[6] Beck explains that in optic neuritis,

> Visual loss in optic neuritis is typically sudden and is associated with pain on eye movement. The visual deficit usually reaches its maximum level within 1 to 7 days. Over time, vision begins to improve, and in most patients visual recovery is considerable…Even when visual acuity recovers to 20/20, mild deficits in other measures of visual function (e.g., contrast sensitivity and color vision) are common.

Resp't. Ex. A.6.

[6] Roy Beck et al., *The Course of Visual Recovery after Optic Neuritis,* 101 Ophthal. 1771-77 (1994). [Resp't. Ex. A.6].

Dr. Bouffard also stated that petitioner's symptoms, which were listed in her affidavit, including a feeling that a needle is poking her eye, double vision, a gray haze, severe dryness, or a horrible headache over her right eye every day "have nothing to do with her remote history of optic neuritis at all." *Id.* Dr. Bouffard opined that, "These complaints are highly typical to dry eye syndrome, which is a diagnosis long-held by the petitioner. Petitioner's diagnosis of dry eyes pre-dated the vaccination and it is not linked to that exposure." *Id.* Ultimately, he concluded in his first report, that petitioner's optic neuritis only caused "transient (resolving in < 6 months), have not left her with any visual disability," and "are not the source of the complaints cited in her affidavit." *Id.*

In his supplemental expert report, Dr. Bouffard states that petitioner's updated medical records from Dr. Skibell at Arizona Eye on 4/15/2021, 2/27/2023, 6/12/2023, and 9/22/2023 "support his prior assertion that many of petitioner's complaints at the time of her affidavit were indeed due to dry eyes (not residua of optic neuritis) which pre-dated vaccination, pre-dated optic neuritis, and would not reasonably be worsened by vaccination or optic neuritis." Resp't. Ex. C at 1; Pet'r. Ex. 30. Specifically, Dr. Bouffard cites improvement of petitioner's eye pain and resolution of petitioner's double vision after more intensive treatment for dry eyes as "strongly supporting" his statement that petitioner's ongoing complaints were attributable to her dry eyes, not her history of optic neuritis. Resp't. Ex. C at 1.

However, Dr. Bouffard did not acknowledge petitioner's macular ganglion cell layer thinning finding from her appointment with Dr. Berezovsky on May 26, 2021. *See* Pet'r. Ex. 12 at 43. At that appointment, Dr. Berezovsky noted that petitioner's "right optic atrophy was not obvious when she was initially seen by me," but that after the examination on May 26, 2021, he found evidence of "temporal pallor of the right optic disc, along with thinning of the RNFL and macular ganglion cell layer in the right eye." Pet'r. Ex. 12 at 43.

He acknowledged that petitioner had optic neuritis, however, he denied that the flu vaccine was the cause of petitioner's optic neuritis, and he also concluded that "petitioner's attack of optic neuritis did not result in vision abnormalities lasting six-months or longer." Resp't. Ex. C at 2.

IV. Discussion and Findings of Fact

Petitioner received the influenza vaccine on October 9, 2019. Pet'r. Ex. 2 at 25. She was diagnosed with optic neuritis on or around November 5, 2019. *See* Pet'r. Ex. 5 at 53. Respondent's expert, Dr. Bouffard, acknowledged that petitioner was diagnosed with optic neuritis. Resp't. Ex. C at 2. Additionally, petitioner's diagnosis of optic neuritis was confirmed by an MRI of orbits which showed a "mildly increased FLAIR signal abnormality in the mid and anterior aspect of the right optic nerve" with accompanying contrast enhancement. *Id.* at 46. There is also no question that her symptoms associated with right optic neuritis, such as right eye pain and visual disturbances, began after the flu vaccine she received on October 9, 2019. *See* Resp't. Brief at 3; *see also* Pet'r. Ex. 5 at 29. Thus, the only factual issue to be determine is whether petitioner suffered the residual effects of her optic neuritis for more than six months, a requirement for a claim to be compensable in the Vaccine Program. *See* 42 U.S.C. § 300aa-11.

For petitioner to satisfy the severity requirement, residual symptoms related to optic neuritis would have to persist in petitioner until at least April 9, 2020, six months after the date of vaccination. After a review of petitioner's medical records, affidavits, and expert reports, I find that petitioner has established that she experienced residual symptoms of her optic neuritis for six-months or longer by preponderant evidence.

Respondent argues that petitioner is unable to meet the severity requirement because she responded quickly to steroid treatment and by May 6, 2020, petitioner's vision exam was normal and her vision returned to pre-vaccination baseline. Resp't. Br. at 11-12. On October 31, 2019, petitioner went to Associated Ophthalmologists complaining of constant right eye pain that was affecting her vision. Pet'r. Ex. 5 at 29. After the examination, she was assessed with "orbital pain in or around right eye," and the findings were that she had "some optic nerve fullness in both eyes, right retro-orbital pain, worse with eye movement," and, "possible optic neuritis." *Id.* at 33. Five days later, on November 5, 2019, petitioner went to St. Joseph's emergency department with blurring vision in her right eye and right eye pain. Pet'r. Ex. 9 at 2. Petitioner also explained that she had vertigo, changes in her gait, cloudy view of objects, and "speckles in [the] eye." *Id.* The MRI of her orbits revealed a "mildly increased FLAIR signal abnormality in the mid-and-anterior aspect of the [right optic nerve] also demonstrating contrast enhancement." *Id.* at 7. She was prescribed a five-day course of IV steroids and a prednisone taper. See Pet'r. Ex. 9 at 9-10.

Even though at a follow-up appointment with Dr. Skibell on November 13, 2019, he indicated petitioner's symptomology was "improving status post-course of IV steroids, six days later, petitioner called Dr. Skibell complaining of "worsening eye pain with movement" as she was tapering from a steroid dosage of 20 mg to 10 mg. Pet'r. Ex. 9 at 35. She was instructed to maintain her steroid dosage at 20 mg. At her next appointment on January 29, 2020, Dr. Al-Hasan noted that petitioner's primary symptoms of her optic neuritis that began in November 2019 were "subacute loss of vision and loss of color saturations involving the right eye." Pet'r. Ex. 11 at 9. He observed that petitioner had significant improvement but was still experiencing blurring in her right eye compared to her left. *Id.*

Petitioner's next appointment on May 6, 2020 with Dr. Al-Hasan was seven months post-vaccination. This appointment was a telehealth appointment due to the COVID-19 Public Health Emergency. Pet'r. Ex. 11 at 42. After the video appointment, he referred petitioner to neuro-ophthalmology and diagnosed her with "subacute optic neuritis." *Id.* at 44. At her appointment with neuro-ophthalmologist, which again was a telehealth appointment, Dr. Berezovsky on June 24, 2020, noted that she once again reported that her vision had improved but that it was "not back to her previous baseline," and that "her right eye vision frequently fluctuates." *Id.* at 20. On April 15, 2021, petitioner had a follow-up appointment with Dr. Skibell when he wrote that petitioner did not have any thinning of the retinal nerve fiber on the optical coherence tomography ("OCT") measure, but noted "some decrease compared to 2019." Pet'r. Ex. 5 at 11. Additionally, when petitioner had a follow-up with Dr. Berezovsky on May 26, 2021, he noted that he had not initially found "right optic atrophy" at his first examination of petitioner in 2020, but observed at this examination a "temporal pallor of the right optic disc, along with thinning of the retinal nerve fiber layer and macular ganglion cell layer in the right eye,." Pet'r. Ex. 12 at 43.

Respondent, through Dr. Bouffard, appears to argue that the only residual effect or symptom that could establish the six-month severity requirement is loss of vision. However, this limited view is inconsistent with the interpretation of the meaning of "residual effects" and "complications" of §300aa-11(c)(1)(D). In *Wright,* the Federal Circuit clarified that "residual" suggests something remaining or left behind from a vaccine injury and that Congress contemplated that "residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." *Wright v. Sec'y of Health & Human Servs.,* 22 F.4th 999, 1005 (Fed. Cir. 2022). The Court also explained that "complication" appears to mean "[a] morbid process or event occurring during a disease which is not an essential part of the disease, although it may result from it." *Id.* at 1006 (citing *Abott v. Sec'y of Dep't of Health & Hum. Serv.,* 27 Fed. Cl. 792, 794 (1993). "Read together, "residual effects" and "complications" appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease, or may be outside the ordinary progression of the vaccine injury." *Id.* Not only was petitioner complaining of *symptoms* consistent with her optic neuritis past six months, such as frequently fluctuating vision in her right eye or "colors jumping around the page," but also demonstrated *signs* of residual injury from optic neuritis in the form of "temporal pallor of the right optic disc, along with thinning of the retinal nerve fiber layer and macular ganglion cell layer in the right eye" at her appointment with Dr. Berezovsky in May 2021. *See* Pet'r. Ex. 12 at 20, 41-43.

As explained by petitioner's expert, Dr. Mackay and supported by the article by Sabadia et al., the finding of thinning of the retinal nerve fiber layer after optic neuritis results in low-contrast visual acuity and a "decreased sharpness to the vision that can interfere with daily activities." Pet'r. Ex. 25 at 3; Pet'r. Ex. 35 at 4. Sabadia explains that retinal nerve fiber layer thinning is observed in 74% of affected eyes in optic neuritis and can be found as early as one month after onset of acute optic neuritis. Pet'r. Ex. 35 at 4. Furthermore, the thinning of the retinal nerve fiber layer and ganglion cell layer "is present even among eyes of patients traditionally characterized as having good visual recovery," and that even when "high-contrast visual acuity recovery after optic neuritis is 20/40 or better, there are clinically meaningful reductions in vision-specific quality of life that reflect persistent impairment of low-contrast letter acuity and losses of retinal nerve fiber layer and ganglion cell layer thickness….This is consistent with the clinical observation among neuro-ophthalmologists that patients perceive visual deficits long after the acute optic neuritis event and achievement of maximal recovery." Pet'r. Ex. 35 at 4. Thus, the finding of thinning of the retinal nerve fiber layer *and* petitioner's persistent visual impairments are consistent with the residual effects of optic neuritis, even as her vision returned to baseline.

Petitioner's initial symptoms of her optic neuritis consisted of vision loss, blurry vision, speckles in her eyes, cloudy view of objects, pain over her right eye, and loss of color saturation. *See* Pet'r. Ex. 9 at 2; *see also* Pet'r. Ex. 11 at 9. Even as petitioner's vision improved to baseline, she still experienced other lingering symptoms of the optic neuritis, including "frequently fluctuating vision in her right eye," a "gray haze," "light sensitivity," "right eye pain" and "colors jumping around on a page," past April 2020. *See* Pet'r. Ex. 12 at 41, 43. Additionally, the documented thinning of petitioner's right retinal nerve fiber layer macular ganglion cell layer of the right eye was an observable lingering sign of petitioner's optic neuritis that coincided with

ongoing symptoms of visual disturbances, right eye pain, light sensitivity, and colors jumping around on paper. Pet'r. Ex. 12 at 41, 43.

Based on petitioner's persistent reporting of symptoms after April 2020 that were consistent with her initial presenting symptoms of optic neuritis and the residual signs of the optic neuritis found by petitioner's treating neuro-ophthalmologist, petitioner has met the severity requirement of the Vaccine Act.

Lastly, respondent's argument that petitioner's complaints of "eye pain, double vision, and a 'gray haze' at the time she authored her affidavit on June 14, 2021" were a result of petitioner's pre-existing dry eye syndrome diagnosis and not residual effects of petitioner's optic neuritis is unpersuasive. Resp't. Br. at 13. It is not disputed that petitioner was diagnosed with dry eye syndrome prior to her vaccination on October 9, 2019 and that she continued to suffer from dry eyes into 2023 which caused symptoms like dryness and itching but not likely double vision or gray haze. *See* Pet'r. Ex. 30 at 139. Additionally, Dr. Mackay, petitioner's expert, agreed with respondent's expert Dr. Bouffard that "some of the petitioner's symptoms are more likely to be from a cause other than optic neuritis, such as dry eyes." Pet'r. Ex. 25 at 3. However, both petitioner's treating physicians and her expert, Dr. Mackay, were able to separate her symptoms associated with dry eye and the residual symptoms of her optic neuritis.

The record indicates that petitioner's treating physicians associated her complaints of "irritation, itching, and redness" with dry eye. *See* Pet'r. Ex. 5 at 7; Pet'r. Ex. 30 at 138. Furthermore, petitioner reported that the treatment for her dry eyes with artificial tears and discontinuation of her contact lenses was effective, however, she still experienced ongoing "visual disturbances" such as "colors on a paper page "jumping around." *See* Pet'r. Ex. 12 at 41. Her treating ophthalmologist, Dr. Berezovsky diagnosed petitioner with right optic neuritis after finding thinning of the retinal nerve fiber layer and of the macular ganglion cell layer, but he noted that she had a "component of dry eyes that was responding to treatment." *Id.* at 43. Petitioner's most recent records establish that after intensive dry eye treatment, petitioner reported that "her eye pain had resolved, and she denied any further double vision." Pet'r. Ex. 30 at 154-158. Therefore, I find that petitioner's symptoms of irritation, itching, and redness are associated with her dry eye syndrome and not her optic neuritis. However, petitioner's complaints of a "gray haze" and her "peripheral vision being off" are attributable to her history of optic neuritis. None of petitioner's treating physicians attributed these symptoms to dry eye syndrome, and petitioner's expert Dr. Mackay credibly explained that those symptoms are "exactly what I would expect after a history of optic neuritis." Pet'r. Ex. 25 at 3. Therefore, I find that petitioner's complaints of a right eye visual fluctuations, gray haze, and decreased sharpness to vision are contributable to her diagnosed optic neuritis and not to her dry eyes, which pre-dated the vaccination.

Based on the record as a whole and after weighing the available evidence, I find that petitioner does meet the six-month severity requirement. The medical records demonstrate that she suffered residual signs and symptoms of optic neuritis through at least June 2021, over 1.5 years after the date of vaccination. Petitioner's statements contained in her affidavit support the medical records, namely her complaints of a "gray haze" and her "peripheral vision being off. As

a result, petitioner has demonstrated by preponderant evidence that she experienced relatively mild residual effects of her optic neuritis for more than six months after vaccination.

V. Conclusion

Upon review of the record as a whole, petitioner has provided evidence to satisfy the severity requirement**.**

The following is **ORDERED:**

1) The parties shall file a joint status report proposing further proceedings **within 30 days, by Thursday, September 19, 2024.**

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master